



Manufacturing ERP for Medical Device Manufacturers

ERP that provides the control,
flexibility, and scalability to
succeed in an ever-changing
regulatory environment.

In medical device manufacturing, even the slightest inaccuracies can cost more than money - they can cost lives. Complying with stringent standards in quality, safety, and traceability can be the biggest hurdle where medical device manufacturers and healthcare industries fail. Complex raw materials, precise production techniques, and proper packaging require manufacturers to strictly control critical shop floor operations.

Population demographics, medical knowledge, and technological advances drive demand in the medical device manufacturing industry. A company's profitability can skyrocket with the ability to develop superior products quickly. OptiProERP with SAP Business One unlocks this potential for growth and success, providing the functionality needed to meet current and future needs.



Common Challenges for Medical Device Manufacturers

- Quality issues in the product design or materials used in production
- Managing supply chain disruptions from local and global suppliers
- Achieving a high level of traceability while also meeting regulatory standards
- Managing complex manufacturing processes for intricate products
- Need for solid financial controls with multiple compliance reports
- Inability to easily define, build, and sell “kitted” inventory items

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With OptiProERP and SAP Business One, we'll gain the efficiencies needed to help us grow to become the market leader in the small bowel capsule market and enter new diagnostic markets once we gain additional FDA approvals.

Johnny Wang

President, CapsoVision, Inc.

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OptiProERP with SAP Business One Critical Benefits for Medical Device Manufacturers

OptiProERP, a modern manufacturing ERP software, is built on SAP Business One, the leading ERP for small and midsize enterprises with over 85,000 customers. It provides end-to-end functionality and best-in-class business and industry capabilities, offering medical device manufacturers a comprehensive solution to streamline and connect all aspects of their business.



Deep and End-to-End Industry Functionality

A fully integrated manufacturing ERP solution for medical device manufacturers manages and streamlines all business operations. Departments are connected for greater efficiency, including sales, production, quality, and purchasing.



OptiProERP with SAP Business One provides end-to-end visibility, advanced manufacturing functionality, and best-practice business processes for the medical device industry. It delivers increased data for real-time insight into business performance to make better-informed decisions.

Optimized Production with Planning, Scheduling, and Shop Floor Execution

Balance demand, capacity, and constraints with advanced planning and scheduling to generate achievable production schedules. Take all resources, including machines, into account to improve equipment usage and minimize resource downtime.

In planning, visualize what production will look like based on “what if” scenarios—capture plant floor data and leverage it to accelerate throughput and quality. Improve on-time deliveries with accurate scheduling for greater customer satisfaction.

Strong Quality Management to Ensure Compliance with Regulations

OptiProERP meets stringent compliance and regulatory standards and provides complete traceability to ensure product safety. It maintains the entire product history from development to delivery, including cradle-to-grave lot and serial number traceability, and serial genealogy of component products. OptiProERP also maintains a complete audit trail of manufacturing processes.

You can meet high-quality expectations for medical devices with proactive quality assurance programs. Run tests at any point in production, from inbound raw materials to outbound finished goods. Set up custom inspection plans and schedules and define inspection attributes. Use dashboards to monitor quality events.



Real-Time Inventory Status with Inventory and Warehouse Management

Real-time status and location of inventory to include materials, parts, work in process, and finished goods. Keep optimal levels of inventory by knowing lead times for procurement and production. Inventory and accounting are integrated, so stock levels are adjusted, accounts are credited or debited, and inventory discrepancies are noted.

Execute transactions and track activity using the mobile app and hand-held scanners with barcodes or QR codes for greater efficiency. The system suggests alternative scenarios for materials considered critical for an expedited order or materials that have been delayed to keep projects on track. Eliminate stock outages, reduce unused inventory, and lower carrying costs. Ensure sufficient stock levels to maintain production schedules.

Increase Revenue and Reduce Costs by Effectively Managing Kitting

Inventory management in OptiProERP provides kitting functionality, which groups items into kits, defines kit pricing, and updates inventory for the individual items in the kits. Kitting can help improve efficiency by having everything needed for a particular task ready in preassembled kits.

A single SKU can define a collection of items stored separately in the warehouse. When an order is received, the individual components are picked and packaged together to fulfill the order, or they can be preassembled. Inventory kitting gives more flexibility to create a variety of kits that customers want. It can help move stock that isn't selling by combining it with other items to make it more appealing.

Manufacturing kitting involves compiling raw materials and components required to make specific products. This ensures that the production team has everything it needs for manufacturing. Kitting helps to reduce errors, save warehouse space, lower costs, and increase revenue.

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OptiProERP with SAP Business One provides strong financial acumen and inventory management and meets the compliance needs of fast-growing medical device and biotechnology firms.

Vivian Tsai

Accounting Manager, CapsoVision

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OptiProERP with SAP Business One Functionality Medical Device Manufacturers Need

Financial Management



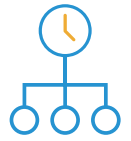
- Manage and forecast cash flow, control budgets, and monitor job costs.
- Use real-time reporting with either standard or customized reports for better-informed decisions.
- Track fixed assets through a virtual function to eliminate manual entries.
- Post and create journal entries and allocate them to a project or profit center.
- Track all banking processes and easily reconcile accounts.
- Accelerate your financial close and utilize role-based dashboards.

Sales & CRM



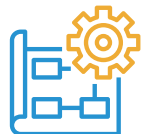
- Reps can track all opportunities and lead activities throughout the sales cycle.
- Create, manage, and analyze marketing activities to help turn prospects into customers.
- All critical customer information is stored in one place to assist customers quickly.
- A mobile app lets sales reps work from their mobile devices anytime and anywhere.

Production Management



- Bill of Materials (BOM) lets you build a comprehensive list of materials, resources, and costs to complete a job.
- Manage revisions or create alternate BOMs to ensure updated documents get associated with the correct production orders.
- Use alternate BOMs to create engineering change orders and automatically update all changes.
- Managers can monitor workers' and machines' performance and job status for any work center.
- Identify and track direct and indirect costs for material resources and labor.
- Use production move orders to automate requests to move materials from one onsite location to another while keeping track of the inventory.
- Set up tooling specifications for machines to monitor performance and maximize capacity.

Materials Requirements Planning (MRP)



- Use MRP to automate purchasing and production to ensure inventory levels are available when needed.
- Working backward, the planning engine automatically calculates materials, resources, and capacity needed to complete each step.
- Forecast inventory demand by sales order, historical sales patterns, or to meet minimum stock requirements.

- Define total operational capacity based on machines, tooling, and available resources.
- Work with projected and actual supply chain demand to create production, purchasing, and inventory schedules.
- Working within a predefined operational capacity, the Resource Planning tool allocates work based on the capacity of available resources.

Quality Management



- Execute quality management across receiving, production, and shipping to identify and resolve issues proactively.
- Use MRP to automate purchasing and production to ensure inventory levels are available when needed.
- Track raw materials, work in progress, and finished goods to expedite negotiated pricing or return of supplies.
- Conduct QC and capture data from any location via mobile and web.
- Streamline post-inspection processes to quickly determine when received goods are faulty.
- Execute inspection plans, checklists, and QC tests against products, people, and equipment.
- Track non-conformances, maintain a complete audit trail, and manage corrective and preventive action processes.
- Carry out 100% inspection or sampling routines for AQL and non-AQL throughout processes.

- Implement forward and backward tracing of all serial or lot number movements.
- Evaluate and rank vendor/supplier performance through key performance indicators (KPIs).
- Document internal controls, security, quality measures, and document searches and retrievals for audits or inspections.
- Receive multi-level notifications and historical tags with automated changes to policies, procedures, and more.
- Support the complete audit from beginning to end in compliance with corporate standards and industry regulations.
- Report with user-friendly and pre-built reports for vendor, production, and stability analytics.

Warehouse Management System



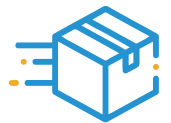
- Issue materials for delivery or production using the mobile app.
- Record receipt of goods from vendors or the shop floor.
- Capture cycle or physical inventory counting for real-time status of on-hand stock and set replenishment alerts.
- Execute transactions and track activity using the mobile app and hand-held scanners with barcodes or QR codes.

Shop Floor Execution



- Manage labor, machines, and materials for optimal shop floor performance.
- Include documents, drawings, and videos as attachments for work instructions.
- Operators utilize touch screens to log in, start work, manage tasks, and report job status.
- Supervisors use the mobile app to monitor production status from anywhere and assign workers with a specific skill set to a particular machine.

Shipping



- Supports all major carriers.
- Validate addresses and create shipping quotes and shipping labels.
- Use a consignee account for shipments.
- Scan the Bill of Ladings.
- Track shipments, cancel shipments, and create a pickup request.
- Use international shipping and support for multi-language and currency.
- Print shipping labels in batches.
- Receive email notifications on the progress of shipments.
- See rates for different shipping options.

Planning and Scheduling



- Work with projected and actual supply chain demand to create production, purchasing, and inventory schedules.
- Identify demand for multi-plant entities and consolidate orders for efficient procurement.
- Explode the planning BOMs and do the same for lower-level items in the production plan.
- Visualize and interact with your production schedule, clicking and dragging to automatically move production orders and update schedules.
- Use 'what if' simulations to see how different scenarios impact production.
- Evaluate the effects of future demand changes to see how or if they can be met.
- Consider rough cut capacity, target days of stock cover, re-order quantities, and more for scheduling.
- Model constraints to include primary, secondary, materials, resources, tooling, labor, and machines.
- Implement custom rules about how materials are consumed to ensure sub-assemblies and raw materials are used according to business rules.
- Define schedule optimization rules to deal with problems such as minimizing changeover times, WIP, and stock levels.
- Create order-based schedules and apply ranking or weighting to prioritize orders based on available resources and additional constraints.

- Trace and manage changes, costs, delays, and more.
- Flexible and customizable to set up the way you need.
- Quickly run best practice reports and alerts that are ready out-of-the-box.

Purchasing



- Synchronize goods receipts and inventory and have purchasing processes in a central location to manage detailed data.
- Match documents and view information trails for audit efficiency.
- Use a PO reference to process AP transactions to plan for and purchase needed materials.
- Request vendor quotes, create purchase requests, and pay vendors systematically.
- Set approvals by dollar thresholds, users, departments, and locations.
- Match purchase orders, invoices, and packing slips to ensure accuracy.

Inventory Management



- Maintain the minimum stock needed with real-time reports that utilize past buying patterns to forecast demand.
- Keep track of inventory by physical counting, spot checks, and cycle counting.
- Use ABC item analysis to categorize inventory by highest consumption value, lowest consumption rate, and interclass items.

- Forecast inventory requirements accurately with hindcasting based on historical demand.

Customer and Vendor Portal



- Customers can access their account, order, payment, and service/support information via a web-based, two-way portal.
- Suppliers can log in 24/7 to view purchase orders and other pertinent information.



OptiProERP is an established provider with lots of knowledge, experience, and best practices we can leverage. We liked that OptiProERP uses SAP, which our parent company uses, albeit an enterprise version, and that OptiProERP has an internal implementation team – no third parties.

Marcus Straw

President and CEO, Applied Physics Technologies



OptiProERP Customer Profile: Qvella

Headquarters: Richmond Hill,

Replaced: Simply Accounting

Evaluated: Acumatica

Pain Points:

- They couldn't easily manage the complexities of their products' manufacturing processes and BOMs.
- They couldn't trace products to meet regulatory standards, including FDA and MDSAP for ISO13485 and international regulations.
- They needed strong financial controls to satisfy medical device manufacturing requirements.
- They were ready to go into full-scale production and needed functionality that could support their growth.

Benefits:

- They meet regulatory standards for an ISO13485 environment and for international regulations.

- They streamlined their manufacturing processes and satisfy medical device manufacturing traceability requirements.
- They have strong financial management in place and fast access to their critical reports.
- They got an essential product into commercial production and gained robust functionality to support their continued growth.

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Qvella has a seasoned management team that has used many ERP systems. Very few systems we seriously considered could come close to OptiProERP's capabilities.

Michael Fricker
CFO, Qvella Corp.

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